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ATTORNEY DOCKET NO. CONFIRMATION NO. FIRST NAMED INVENTOR APPLICATION NO. **FILING DATE** Michael C. MacLeod UTSC:607USC1 5071 09/840,722 04/23/2001 EXAMINER 7590 02/05/2004 David L. Parker WHISENANT, ETHAN C FULBRIGHT & JAWORSKI, L.L.P. PAPER NUMBER ART UNIT **Suite 2400** 600 Congress Avenue 1634

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) |
|--|---------------------------------------|--|
| Office Action Summary | 09/840,722 | MACLEOD ET AL. |
| | Examiner | Art Unit |
| | Ethan Whisenant, Ph.D. | 1634 |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | |
| Status | | |
| 1) Responsive to communication(s) filed on <u>07 November 2003</u> . | | |
| 2a)⊠ This action is FINAL . 2b)☐ This | action is non-final. | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | |
| Disposition of Claims | | |
| 4) Claim(s) 3,4,20,21,23-29,36-76 and 85-89 is/are pending in the application. | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | |
| 5)⊠ Claim(s) <u>3-4, 20-21,23-29, 36-76 and 85-86</u> is/are allowed. | | |
| 6)⊠ Claim(s) <u>87-89</u> is/are rejected. | | |
| 7) Claim(s) is/are objected to. | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | |
| Application Papers | | |
| 9) The specification is objected to by the Examiner. | | |
| 10) \boxtimes The drawing(s) filed on <u>23 April 2001</u> is/are: a) \boxtimes accepted or b) \square objected to by the Examiner. | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage | | |
| application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. | | |
| 37 CFR 1.78. | | |
| a) The translation of the foreign language provisional application has been received. | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. | | |
| Attachment(s) | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | · · · · · · · · · · · · · · · · · · · | (PTO-413) Paper No(s) atent Application (PTO-152) |
| 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) Other: | | |

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FINAL REJECTION

1. The applicant's Response (filed 07 NOV 03) to the Office Action has been entered. Following the entry of the claim amendment(s), Claim(s) 3-4, 20-21, 23-29, 36-76 and 85-89 is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

CLAIM REJECTIONS UNDER 35 USC § 102/103

- 2. Claim(s) 87-89 is/are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Senapathy [US 5,994,058 (1999)] for the reason of record.
- 3. Claim(s) 87-89 is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Silver et al. [US 5,104,792 (1992)] for the reason of record.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

- **4.** Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are deemed to be only persuasive in part. The following prior art rejections have been withdrawn in light of the applicant's claim amendment(s) and the persuasive arguments in the response file 07 NOV 03:
- ► The rejection of Claim(s) 20, 23-24, 27-29, 36-38, 45-46, 50, 71-72, 85, and 87-89 under 35 U.S.C. 102(e) as being anticipated by Kuipier et al. [US 5,874,215 (1999)].
- ► The rejection of Claim(s) 3-4 under 35 U.S.C. 103(a) as being unpatentable over Kuipier et al. [US 5,874,215 (1999)].

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► The rejection of Claim(s) 39-44 and 47-49 under 35 U.S.C. 103(a) as being unpatentable over Kuipier et al. [US 5,874,215 (1999)] as applied against Claim 36 above and further in view of Matthews et al. (1988).

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As regards the 102(e)/103(a) rejections the examiner has fully and carefully considered the claim amendments to Claims 87-89 and the comments presented in the response filed 07 NOV 03. The examiner is not persuaded, therefore, these rejections have been maintained. Could not the predetermined 5' sequence of the primers taught by Senapathy [US 5,994,058 (1999)] and/or Silver et al. [US 5,104,792 (1992)] anneal to a predetermined linker sequence if such sequence were presented? The examiner continues to maintain that this limitation is an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The primers taught by Senapathy and/or Silver et al. are capable of performing the intended use given the proper nucleic acid sequence. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). For example, look at Column 3 line 55-57 of Silver et al. and note the five nucleotides just 5' of the region comprising the 3' random nucleotides. This sequence 5'- GACTCNNNN-3' will, if provided a linker sequence of 5' - XXXXGAGTC- 3' anneal thereto. Therefore it can be said that the primers taught by Senapathy and/or Silver et al. are capable of performing the intended use.

CONCLUSION

- **5.** Claim(s) 3-4, 20-21, 23-29, 36-76, and 85-86 is/are allowable while Claims 88-89 is/are rejected and/or objected to for the reason(s) set forth above.
- **6.** THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (571) 273-0754. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

ETHANWHISENANT PRIMARY EXAMINER

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